August 12, 2004

Anne P. LeHuray, Ph.D.
Technical Contact
The American Chemistry Council
Rubber and Plastic Additives Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. LeHuray:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Sodium Dimethyldithiocarbamate posted on the ChemRTK HPV Challenge Program Web site on February 4, 2004. I commend The American Chemistry Council Rubber and Plastic Additives Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Dr. Ralph Northrop, of the HPV Chemicals Branch, at 202-564-7666. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Sodium Dimethyldithiocarbamate

Summary of EPA Comments

The sponsor, the Rubber and Plastic Additives Panel of the American Chemistry Council, submitted a test plan and robust summaries to EPA for Sodium Dimethyldithiocarbamate (SDMC, CAS No. 128-04-1) dated December 19, 2003. EPA posted the submission on the ChemRTK HPV Challenge Website on February 4, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to provide adequate boiling point data and additional detail from the melting point determination .

2. Environmental Fate. The submitter needs to: identify this chemical's hydrolysis products; provide measured ready biodegradation data; and recalculate the fugacity and provide the input values used.

3. Health Effects. The submitted data for acute, genetic, and repeated-dose toxicity endpoints appear adequate for the purposes of the HPV Challenge Program. EPA reserves judgement on the adequacy of the reproductive and developmental toxicity endpoints until it receives the robust summaries for these endpoints.

4. Ecological Effects. For the purposes of the HPV Challenge Program, the submitted data on all ecological endpoints appear adequate; however, the robust summaries need to be enhanced with additional information.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Sodium Dimethyldithiocarbamate Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitter's melting point value (110 °C, determined by differential scanning calorimetry (DSC)) differs significantly from a value EPA located in the literature (57-58 °C, Tashchi et al, 1982). Because the submitter did not characterize the identity (e.g., % hydration) or the purity of the test substance, and did not provide experimental details such as the chemical isolation method and the nature of the DSC curve, the difference cannot be accounted for by the submitted data. The submitter needs to provide more detail in the robust summary to help resolve this issue.

Boiling point. The submitter provided a boiling point of 102 °C for a 32% aqueous solution of sodium dimethyldithiocarbamate (SDMC, Vanderbilt 1990). However, this reflects the boiling point of water rather than SDMC. The submitter needs to provide measured boiling point data for the pure form of this chemical. An estimated value is acceptable if it is above 300 °C. If this chemical decomposes before reaching the boiling point, then this value should also be reported by the submitter. Values obtained from published literature sources are adequate as long as the submitter identifies the source.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation are adequate for the purposes of the HPV Challenge Program.

Stability in water. The submitter needs to identify the hydrolysis products in its robust summary.

Biodegradation. The submitter provided information from one anaerobic biodegradation test by a standard EPA method, OPPTS 835.4400 and GLP. However, this is not a ready biodegradation test. For the purposes of the HPV Challenge Program, the submitter needs to provide measured ready biodegradation data for SDMC, with the following stipulations to reduce the possible complications from hydrolysis and antimicrobial activity while retaining environmentally relevant conditions: (1) select a method with relatively low initial concentration (e.g., 301B or (better) 301D); (2) adjust the pH to 8 and measure it throughout the test, along with the other usual measurements.

Fugacity. The submitter needs to recalculate its fugacity model using measured melting point and boiling point values if available. The use of estimated values introduces uncertainties that then become magnified in modeling applications. The submitter needs to include in its fugacity robust summary all input values used in its estimation.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted data for acute, genetic, and repeated-dose toxicity endpoints appear adequate for the purposes of the HPV Challenge Program. The submitter needs to submit robust summaries for reproductive and developmental toxicity endpoints that were omitted from the submission. EPA reserves judgement on the adequacy of these endpoints until these data are submitted and reviewed. In addition, the submission includes an unfinished summary for a mouse 17-month carcinogenicity study. The submitter either needs to complete this summary or delete it from the submission.

Ecological Effects (fish, invertebrates, and algae)

Although the submitted studies appear adequate, some critical information on test conditions and results were not included. The submitter needs to provide necessary information in robust summary format to allow an independent evaluation of these studies.

Specific Comments on the Robust Summaries

Ecological Effects

Details missing from all these summaries included whether the reported toxicity is for the commercial product or 100% active ingredient, the identity and amount of inert chemicals, concentrations tested, number of animals used per concentration, mortality and effects per concentration, use of control and its response, and the water chemistry parameters.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

References

Tashchi VP; Ivanov AP; Rukasov AF; Putsykin YG; Orlova TI; Baskakov YA. *J Org Chem USSR* (Engl Transl), CODEN: JOCYA9, 18(10), <1982>, 1930-1937, Zh Org Khim, CODEN: ZORKAE, 18(10), <1982>, 2190-2197. {BEILSTEIN On-line}.

R.T. Vanderbilt study; Baron consulting, 1990